

ASPIRIN 81MG- aspirin tablet, chewable
Gendose Pharmaceuticals, LLC

Active ingredient (in each tablet)

Aspirin 81 mg (NSAID**)

**nonsteroidal anti-inflammatory drug

Purpose

Pain Reliever

Uses

- for temporary relief of minor aches and pains or as recommended by your doctor.
- ask your doctor for other uses of this product.

Warnings

Reye's syndrome:Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert:Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

Stomach bleeding warning:This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Do not use

- if you are allergic to aspirin or any other pain reliever/fever reducer.
- this product for at least 7 days after tonsillectomy or oral surgery unless directed by a doctor.
- if you have ever had an allergic reaction to this product or any of its ingredients.

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma

Ask a doctor or pharmacist before use if you are

taking a prescription drug for

- gout •diabetes •arthritis

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
- have stomach pain that does not get better
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- ringing in the ears or a loss of hearing occurs

If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use aspirin at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- drink a full glass of water with each dose
- **adults and children 12 years and over:**take 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor
- **children under 12 years:**consult a doctor

Other information

- store at 25 °C (77 °F); excursions permitted between 15°-30°C (59° - 86°F)

Inactive ingredients

dextrates, FD&C yellow #6 aluminum lake, orange flavor, saccharin sodium, corn starch

Principal Display Panel

NDC 77333-049-20

**Compares to the active ingredient in BAYER®
Chewable Aspirin LOW DOSE 81mg***

*This product is not manufactured or distributed by the owner of the registered trademark Bayer®

Aspirin 81mg

Chewable Tablets

Orange Flavor

UD 150 Tablets (15x10)



(01) 0 03 77333 049 20 5

 **GenDose®**
Pharmaceuticals

NDC 77333-049-20

Drug Facts

Active ingredient (in each tablet)	Purpose
Aspirin 81mg (NSAID)**	Pain Reliever
** nonsteroidal anti-inflammatory drug	

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Allergy alert: Aspirin may cause a severe allergic reaction which may include:
• hives • facial swelling • asthma (wheezing) • shock

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you: • are age 60 or older • have had stomach ulcers or bleeding problems • take a blood thinning (anticoagulant) or steroid drug • take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) • have 3 or more alcoholic drinks every day while using this product • take more or for a longer time than directed

Do not use • if you are allergic to aspirin or any other pain reliever/fever reducer • this product for at least 7 days after tonsillectomy or oral surgery unless directed by a doctor • if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if • the stomach bleeding warning applies to you • you have a history of stomach problems, such as heartburn • you have high blood pressure, heart disease, liver cirrhosis, or kidney disease • you are taking a diuretic • you have asthma

Ask a doctor or pharmacist before use if you are taking a prescription drug for • gout • diabetes • arthritis

Stop use and ask a doctor if • an allergic reaction occurs. Seek medical help right away. • you experience any of the following signs of stomach bleeding: • feel faint • vomit blood • have bloody or black stools • have stomach pain that does not get better • pain gets worse or lasts more than 10 days • fever gets worse or lasts more than 3 days • redness or swelling is present • new symptoms occur • ringing in the ears or a loss of hearing occurs

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LB04920X11

ASPIRIN 81MG

aspirin tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77333-049
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg

Inactive Ingredients

Ingredient Name	Strength
DEXTRATES (UNII: G263MI44RU)	
FD&C YELLOW NO. 6 ALUMINUM LAKE (UNII: GYP6Z2JR6Q)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	AZ013
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77333-049-20	150 in 1 CARTON	05/01/2025	
1	NDC:77333-049-25	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	05/01/2025	

Labeler - Gendose Pharmaceuticals, LLC (080257510)

Establishment

Name	Address	ID/FEI	Business Operations
Allegiant Health		079501930	manufacture(77333-049)

Revised: 4/2025

Gendose Pharmaceuticals, LLC